THE UNIVERSITY OF SOUTHERN MISSISSIPPI
ANIMAL CARE AND USE HANDBOOK
Revised October 17, 2005

THE UNIVERSITY OF SOUTHERN MISSISSIPPI INSTITUTIONAL ANIMAL CARE AND USE (IACUC) HANDBOOK

I. The University of Southern Mississippi IACUC Membership

A. Composition of IACUC

The composition of the IACUC conforms to the overlapping, yet distinctive, requirements of the USDA and the PHS. The Committee is composed of at least five members appointed by the Institutional Official, in this case the Vice President for Research and Economic Development, and includes the following:

- One member is the Veterinarian of Record.
- One faculty member that is a non-scientist.
- At least one public member represents community interests. The public member(s) is not a laboratory animal user, is not affiliated with the institution, and is not a member(s) of the immediate family of a person who is affiliated with the institution.
- There is at least one practicing scientist experienced in research involving animals.
- Not more than three members are from the same department.
- Ex officio non-voting members of the committee include the Director of Animal Facilities, the JST Animal Facilities Manager, a representative of the Sponsored Programs Administration, and the IACUC administrative assistant.

Each member is appointed for three years and may serve consecutive terms. The IACUC reports directly to the Institutional Official.

B. Roles and Responsibilities

The IACUC is responsible for reviewing all research in which animals serve as research subjects as well as the use of animals in teaching. IACUC oversight covers all use of live animals in research and teaching, whether in the laboratory or in the wild as a part of field research. Once approved, the IACUC maintains continuing oversight of the approved projects on an on-going basis and requires an annual review and a complete resubmission on a triennial basis to both comply with the regulations as well as to vigilantly oversee the use of animals. Not only is the IACUC responsible for ensuring that the protocols conform to acceptable standards and the regulations, it also ensures that the animal care program is in compliance. In this regard, the IACUC undertakes semi-annual program reviews and facilities inspections. The results of these reviews are communicated to the Institutional Official for his/her consideration and action where necessary. Additionally, they form the basis for the required annual reporting to the Office of Laboratory Animal Welfare (OLAW) and the United States Department of Agriculture (USDA). As part of its charge, the IACUC is expected to oversee the program on a continual basis and to report problems to the Institutional Official and, as necessary, to report unapproved variances from the standards of animal care and use promptly to the oversight agencies.

Its many responsibilities can be summarized under six main groupings:

- Review, prior to their initiation, of all proposed projects at the University involving vertebrates; review is conducted with respect to the humane care and use of animals and compliance with all applicable laws, regulations, and guidelines;

- Inspection of facilities where animals are housed or animal work is done;
- Review and make recommendations regarding any aspect of the University's animal care program;
- Ensure the University's compliance with federal, state, and local regulations pertaining to animal use;
- Set general University of Southern Mississippi policy on humane care and use of laboratory animals;
- Prepare the annual OLAW assurance update, semiannual inspection reports, and assistance in preparation of the "Annual Report of the Research Facility" which is submitted by the Institutional Official to the USDA.

Although the IACUC functions to ensure that animals are utilized in a humane fashion, the responsibility for this rests with those individuals performing the research, the principal investigator and staff. The IACUC serves an important function 1) to ensure the care and well being of research animals, and 2) to safeguard a biomedical researcher's privilege to use animals by protecting the principal investigator and the institution. The Committee is dedicated to maintaining an open dialogue with investigators to achieve these goals, and it is the Committee's hope that investigators will see it as a resource for this purpose.

II. Roles and Responsibilities of Principal Investigators and Research Staff

A. Serving as a Principal Investigator on an Animal Protocol

While all members of a research team must be adequately trained and fully understand the proposed research project, it is the Principal Investigator (PI) who is responsible for the implementation of the protocol, for the actions of his/her research staff, and for ensuring that all policies of the IACUC are followed. The PI of an animal protocol is responsible for all aspects of the research contained therein. All correspondence regarding their protocols from the IACUC, including results of Committee deliberations and annual surveys, are directed to the PI because of his/her special role. Because of these responsibilities and the importance of compliance to the institution, the PI on all submitted protocols must be a member of the University of Southern Mississippi faculty or professional staff. Students may be included as qualified personnel on a protocol if the principal investigator on that protocol assures their qualifications.

B. Principal Investigator Responsibilities

A PI is accountable for all aspects of the development and implementation of a protocol. While this list is not complete, PI responsibilities include:

- Development and submission of an IACUC protocol and ensuring that no research is initiated until IACUC approval is obtained;
- Responding to the comments of the IACUC;
- Ensuring that all members of the research team are trained in the appropriate and relevant methods, species, and procedures as well as being extremely familiar with this handbook and the IACUC-approved protocol;
- Conducting the protocol as approved;
- Submitting reports as required by the IACUC;
- Maintaining approval for the duration of the project; and

- Submitting any changes to the protocol for approval and initiating changes only after IACUC approval is received. Investigators should note that failure to comply with federal, state, or local regulations on animal use or with university and IACUC policies and procedures may result in suspension of the approved protocol and notification sent to the regulatory agencies and PI funding agencies. Equally important as the result of such a violation to an individual PI, such failure can also jeopardize the University's Animal Welfare Assurance on file with NIH and may lead to revocation of PHS research funding, as well as monetary fines and sanctions imposed by the USDA. Accordingly, it is important for all animal users to recognize that research with animals is a privilege, not a right, and that all parts of the animal use community - PI's, research staff, Sponsored Programs Administration staff, IACUC and the Institutional Official - share a responsibility to protect the institution's ability to continue to conduct animal use.

C. Research Team

The research team listed on a protocol can be composed of co-investigators, fellows, technicians, and students. The research team needs to be listed in the protocol and updated as needed. While the PI is held responsible for all aspects of the conduct of animal use, each member of the research team bears a responsibility to ensure that animals are used in accordance with the protocol, institutional policy, and the ethical principles governing animal use. *Therefore, each member of a research team must receive appropriate training, must understand the protocol, and must be committed to the humane care and use of animals.*

D. Types of Research and Associated Protocol Requirement

1. Use of Live Vertebrate Animals

When live vertebrate animals are proposed for use in research or teaching, a full protocol must be submitted for review. A complete submission will include the basic protocol form as well as relevant appendices.

2. Use of Procured Tissue or Preserved Vertebrates

Research involving only the procurement of tissue from commercial sources or salvaged animals, the use of preserved vertebrates obtained commercially, or obtained from museums does not require IACUC review.

3. Special Considerations

a. Field Studies Involving Animals

Field research, including the capture and tagging of animals, the taking of blood samples, or other invasive or manipulative procedures requires the approval of the IACUC. Investigators who plan to conduct field studies are required to submit an animal protocol to the IACUC for approval.

b. Collaborative Animal Use

Investigators with an appointment at The University of Southern Mississippi who plan to do collaborative animal research with individuals at other institutions are not required to submit an animal protocol if the protocol has already been approved at another institution for work to be completed at the other institution or an offsite location and funding is through the collaborative University unless funding flows through The University of

Southern Mississippi. However, the University of Southern Mississippi requires a copy of the protocol and approval letter from the other institution before work commences. Investigators working on animal research outside the United States should contact the IACUC Chair for assistance. The IACUC would expect the PI's to collaborate only on projects where all of the basic ethical principles of animal care and use still apply.

c. Exempt Animal Use

Several categories of research are exempt from IACUC protocol review. These include but are not limited to field research involving only observation with no manipulation, research involving invertebrates, vertebrate eggs, tissues from colleagues who have protocols that are approved for the harvesting and sharing of such, and tissues obtained from commercial vendors or salvaged animals (found dead). Also exempt are commercially available "off-the-shelf" blood products, and ecological restoration solely for management purposes (e.g. artificial reef). PI's with questions regarding exemptions should contact the IACUC.

4. The Use of Animals in Teaching

The use of animals in teaching has come under closer scrutiny in recent years. The use of animals in teaching, demonstration or training is reviewed by the full IACUC at a convened meeting unless it falls under one of the previously described exemptions. The IACUC ensures that the use of animals is justified, that due consideration has been given to modeling or other means to communicate the same concepts and that, when appropriate, alternatives are available for students who are uncomfortable with the use of animal models. Committee members are available to discuss proposed courses with the instructors and educate them about various issues or concerns, which may be raised by current or prospective students.

E. New Principal Investigators

1. Before Arrival

New PI's should contact the IACUC Chair to initiate the process for protocol submission and consult with the appropriate animal facilities manager regarding their animal needs, including space and species requirements. Once a faculty appointment is confirmed, a new faculty member may submit protocols. Please note that even if the animal use received approval at another institution, it will require a completely new review by the IACUC of The University of Southern Mississippi. Moreover, as each institution has leeway to interpret the regulations and standards governing animal care and use and each institution has its own culture, prior consultation with the IACUC can be very helpful. Especially in situations where external grants will be transferred to The University of Southern Mississippi or where existing animals will be transferred, it is important to secure an approved protocol as soon as possible. Most agencies will not approve the transfer of an award if the institution cannot provide evidence of IACUC approval.

2. Upon Arrival

Upon arrival, new PI's and their investigative staffs should ensure that they are familiar with the practices and standards of The University of Southern Mississippi. This can include:

- Completing the basic training module and all other training relevant to the facility or type of research;
- Reviewing this handbook and other relevant policy and procedure statements;
- Making sure that all staff are listed on the protocol and that new staff are listed on the protocol under which they will be working. This should be done via an amendment before they begin working with animals;
- Ensuring that new staff has read and understood the protocol.

III. IACUC Protocol Preparation and Review

An animal use protocol is a written description of a planned research or teaching activity in sufficient detail to allow for a review of the proposed research activities by the IACUC. Research protocols should be submitted on the most recent version of the IACUC protocol form, which is available at www.usm.edu/iacuc. Incomplete protocols, protocols containing confusing or highly technical language, or protocols involving excessive and unnecessary detail are unacceptable.

A. Preparing a Protocol for IACUC Review

1. What Should Be Addressed in a Protocol?

A protocol must be sufficiently detailed to permit the IACUC to evaluate the soundness of the procedures proposed and to determine appropriateness of the species, the proposed number of animals, and that alternatives to using animals have been completely searched. The IACUC does not normally conduct a peer review as would a grant review panel, but primarily assures that the research proposed is not trivial. In the uncommon cases where serious questions about the soundness of the procedures are raised, the IACUC may utilize the assistance of qualified scientific consultants. As a general guide, the following special elements should be well justified in the protocol:

a. The University of Southern Mississippi IACUC Pain Code Classifications

The University of Southern Mississippi IACUC has established pain code classifications to classify protocols according to the level of pain or unrelieved distress involved. Investigators who complete a protocol must select the pain code that applies to the proposed work. If more than one classification applies, then an investigator should specify the percentage of animals in each. The definitions of these categories, as described in the protocol form, are as follows:

- Classification I: No pain, distress, or use of pain-killing drugs. (i.e., behavior studies, post-mortem tissue harvest; and routine procedures causing only transitory discomfort such as venipuncture, injections, ear tagging)
- Classification II: Pain/distress **with** appropriate analgesic/anesthesia/tranquilizers. Procedures involving accompanying pain or distress to the animals and for which the appropriate anesthetic (for surgery), analgesic (for inflammation or pain) or tranquilizing drugs are used.
- Classification III: Pain/distress **without** appropriate analgesic/anesthesia/tranquilizers. Procedures involving accompanying pain or distress to the animals and for which the

appropriate anesthetic, analgesics or tranquilizing drugs are not used. If all or a percentage of animals will experience either category II or III, the PI must complete the appropriate appendix to document that alternatives to painful or distressful procedures in animals have been considered.

b. Justifying the Number of Animals

The IACUC has a responsibility to ensure that the number of animals used is the minimum number that is sufficient to achieve the scientific or teaching aims. Toward that end, the protocol asks that PI's justify the number of requested animals in detail. Numbers should be based in a statistically valid power analysis or other specific justification. Investigators may not use more animals than the number approved by the IACUC. As part of its review process, the IACUC considers the appropriateness of the proposed animal numbers for the work proposed. PI's are expected to limit the number of animals to the smallest number which allows meaningful conclusions to be drawn from the research. *In cases such as field research where the PI cannot provide precise numbers or species lists, an appropriate justification should be made including estimates.*

c. Anesthesia

The protocol should outline in detail any proposed anesthesia (type of anesthesia, rate of administration, dosage, timing). The Animal Facilities manager can provide assistance to PI's in determining the most appropriate anesthetic regimen for the species and for the type of procedures. Anesthesia of laboratory animals is an art as well as a science. It is also a serious responsibility. Significant animal pain and distress can result from poorly administered or inadequately monitored or inappropriate anesthesia. Only trained personnel should undertake animal anesthesia. The attending veterinarian is available, not only for consultation in planning an anesthetic regimen, but also for training in administering anesthesia. Anesthesia must conform to the method approved by the IACUC in the specific protocol. Records must be kept (see *Documentation* below).

d. Analgesia

Analgesia is the relief or prevention of pain in the conscious animal. The IACUC can assist in determining the need for analgesia and the appropriate analgesic regimen. The protocol should outline the proposed analgesia to be employed if pain is anticipated. It should be generally assumed that any procedure that would cause pain in humans would also cause pain in laboratory animals, and arrangements must be made to minimize pain. Unrelieved pain or distress is NOT acceptable except in circumstances where they have been scientifically justified and approved by the IACUC. PI's should note that even after analgesic drugs have been administered, animals must be monitored closely for the adequacy and persistence of analgesia. Protocols should describe the plan for monitoring animals and should indicate who on the research team will be responsible for monitoring animals. Contact information is essential; this should be kept up to date. As with anesthetics, it is critical to document the administration of analgesia.

e. Surgery

Any proposed surgical procedures, both survival and nonsurvival, must be fully described in the protocol. Nonsurvival surgery is defined as a surgical procedure from which the

animal does not awaken. Nonsurvival surgery must meet applicable standards (e.g., clean instruments, surgeon appropriately garbed, in a suitable environment). Survival surgery, where the animal recovers from anesthesia, must follow strict standards for aseptic technique and can only be conducted in a suitable environment approved for survival surgery. It is essential that individuals performing surgical procedures be well trained to minimize animal pain and to ensure success of the procedure. Appropriate animal and surgeon preparation, aseptic technique, suitable environment, proper instruments, and knowledge of tissue handling and suturing are all essential components of good surgery. Individuals who need additional training in surgery should contact the IACUC consulting veterinarian. The JST Animal Facilities Manager also can provide training materials on the subject of aseptic surgical techniques.

f. Physical Restraint

Physical restraint may be a requirement of the research. However, such restraint must be made as painless as possible for the animals, should be of as short a duration as practicable and should utilize the most animal-friendly restraint system possible. The need to restrain animals should be fully described and justified in the protocol. Justification is particularly important if the restrain is of a long duration or the restraint mechanism itself is non-standard.

g. Food or Fluid Restrictions

Animal care and use standards require that animals receive food and drink consonant with their species and its natural needs. Any deviation from the standard diet of food or constant availability of water must be scientifically justified in the protocol and approved by the IACUC.

h. Documentation/Records

PI's and their staff bear much of the responsibility to prepare and maintain records of the many aspects of animal care and use that are required by regulation and practice. Such records include, for example, records of: animals received, animals used under each protocol, anesthesia, analgesia, post-procedural care, euthanasia method and date, controlled substance use, training, breeding, basic animal care, and clinical care records. *The IACUC protocol number and expiration date should be clearly posted on all animal cages.*

B. How Protocols Are Reviewed

1. How Long The Review Takes

The IACUC meets monthly on the second Thursday of the month unless there are no protocols to review. In order for a protocol to be reviewed at a scheduled IACUC meeting, it must be received by the IACUC administrative assistant 10 working days prior to the meeting date. Particularly complex or controversial procedures with multiple follow-up questions may need additional review time by the IACUC. Every effort will be made to assist investigators with extenuating circumstances requiring special consideration.

2. Process for the Initial Review of Research Involving the Care and Use of Animals

a. Research Investigator Completes a Protocol Approval Form

The first step in obtaining IACUC approval for research involving animals is for the research investigator to complete the IACUC Protocol Approval Form and all applicable appendices. The signed submission form should be sent directly to the IACUC administrative assistant. An electronic copy should also be submitted as an email attachment. Incomplete or illegible submissions will be returned to the Principal Investigator for resubmission. To avoid the perception of conflict of interest, committee members who are participants in the protocol being reviewed do not participate in the review, deliberations and decisions on those protocols.

b. Routing by the IACUC

The IACUC administrative assistant receives submitted protocols and reviews each protocol for completeness. Incomplete protocols are returned to the Principal Investigator with a short note indicating its deficiency. Complete protocols are given an IACUC tracking number and entered into a computer database. The administrative assistant then routes the protocol, usually via email, to all IACUC members for review before the next IACUC meeting.

c. Designated Member Review

For protocols submitted with an "I" pain classification, a designated review process may be used. The full IACUC committee would receive a copy of the protocol and are given the option of calling for a full review. If after a designated time period (3 working days), no committee member has requested full committee review, the Chair of the IACUC may appoint one or more individuals as designated reviewers. Designated reviewers do not have the authority to disapprove a protocol. They can only approve, require modifications (to secure approval), or request full Committee review. Regardless of pain classification, a full committee review is required to disapprove or deny an animal protocol.

d. Full IACUC Review

Protocols classified II or III must be reviewed at a meeting of the IACUC, defined as a quorum of the total voting membership. A majority of that quorum must vote in favor for it to be officially approved. All animal use protocols brought before the IACUC are approved as submitted, withheld pending minor revisions, or denied with recommendations for major revisions. The starting and ending dates of the approval period will be stated on the approval letter.

1) Approve

The IACUC has determined that, for a particular animal research or teaching protocol, appropriate justification for animal use has been made, a search for acceptable alternatives to animal use has been demonstrated, and methods described are within standard and acceptable guidelines. The IACUC signifies its approval of a research protocol by issuing a letter to the Principal Investigator that the research protocol has been reviewed, approved, and may be conducted.

2) Withheld Pending
Protocols with a review status of "withheld pending" are most typically in need of minor corrections or clarifications. The Chair will write a letter to the Principal Investigator indicating that approval for the protocol is being withheld pending certain minor revisions that must be made to the protocol. The Principal Investigator will be invited to submit these revisions directly to the IACUC Chair.

3) Denial
Research protocols might be denied because:

- The protocol is overly confusing or convoluted and not understood by the IACUC (e.g., poorly written or excessive technical language or jargon);
- Procedures described are not considered acceptable according to current standards and justification made was not sufficient to endorse deviation.
- The Principal Investigator has not convinced the IACUC of his or her capacity (training and experience) to conduct the proposed research; or
- The methods being proposed are clearly inadequate for the research.

A protocol may also be administratively denied when a Principal Investigator has not responded to a request for additional information and/or modifications from the IACUC in a timely fashion (30 days).

e. Granting Agency Requirements and Protocol Submission
Many agencies such as NIH, NSF, DOD and the American Heart Association will not review protocols involving animals unless formal notification of IACUC review and approval has been provided. Other agencies may review and score protocols, but they will withhold funding pending notification of IACUC review and approval is received. PI's are urged therefore to submit the IACUC protocol prior to the submission of a grant application. It is critical that the protocol must reflect all proposed animal use detailed in the corresponding grant application.

f. Questions and Appeals
Any PI may request an appointment with the IACUC Chair, or an opportunity to address the IACUC at a regular or special meeting, for any purpose related to the business of the IACUC. The two most common reasons for such an appointment or hearing are to answer questions concerning protocols in development or research in progress, or to resolve difficulties related to the approval of a protocol. Concerns should be brought to the IACUC Chair. If resolution cannot be reached with the Chair, the Principal Investigator may be scheduled to present his/her case before the IACUC at the next regular meeting or at a special meeting called by the Chair (if the situation warrants). There is no appeal to a decision by IACUC to deny a protocol.

IV. Changes to Approved Protocols

A. Making Modifications to Approved Protocols

In approving a protocol, the IACUC has indicated that the animal use protocol is consistent with the regulations and standards. **Any change to the approved protocol must be submitted as an amendment to the IACUC and approved prior to instituting the change.** Such a request must be in writing and may be in the form of a simple letter detailing the reasons for the modification and the proposed modification. This letter and any supporting documents (such as changes to instruments or informed consent documents) should be sent directly to the IACUC administrative assistant by the PI. The IACUC Chair is empowered to approve requests for modifications that are minor in nature. Requested modifications that are not minor in nature will initiate a review of the revised protocol. As with an initial review, the requested modification may be approved, withheld pending minor revisions, or denied. If approved, the revised protocol will carry the same approval period as the original approval.

Examples of significant changes requiring committee review:

- Proposals to switch from nonsurvival to survival surgery
- Addition of surgery to a protocol
- Increase in the degree of invasiveness of a procedure, pain, or discomfort to an animal
- Addition of prolonged physical restraint
- Changes in/or addition of a species
- Change from immunocompetent to immunocompromised strains of animal
- Changes in key personnel involved in animal procedures (e.g., lead researcher, surgeon, post-procedural caretaker)
- Changes in anesthetic method, the use or withholding of analgesics, or euthanasia method
- Addition of blood sampling
- Major increase in number of animals (normally >10%)

Consultation with the IACUC veterinarian or the IACUC Chair is strongly recommended before submission of any modification.

B. Transfer of a Protocol to Another Investigator

Infrequently, circumstances may warrant that a PI wishes to transfer his/her protocol to another investigator. To affect this change, the PI of record and the proposed PI should jointly submit an amendment to the IACUC, requesting the transfer and explaining the circumstances. If the proposed PI is not currently a member of the approved research team, the amendment request should also contain information on the training and experience of the proposed PI with the protocol, its procedures, and the species. Both the approved and proposed PI should sign the amendment form. If, however, the approved PI has left The University of Southern Mississippi, a simple statement to this effect, rather than his/her signature, is sufficient.

V. Length of Approval, Annual Review Requirements and Triennial Resubmission of Protocols

A. Length of Approval

Although an approved protocol is limited to no more than three years, each protocol must be updated and reviewed "not less than annually".

B. Annual Protocol Status Reports

To comply with the regulations that are outlined in the USDA Animal Welfare Regulations, the IACUC has instituted an annual review process. The Principal Investigator will be contacted on a yearly basis for renewal. Principal Investigators will be sent a letter from the IACUC administrative assistant six weeks before the protocol's annual date requesting an Annual Protocol Status Report which the PI is required to complete, sign and return to the IACUC administrative assistant before the annual date of the protocol. Changes of substance indicated on the annual review form could require an amendment to be submitted. Depending upon the content of the amendment, the amendment request will be reviewed either by the IACUC Chair or full committee process.

C. Triennial Resubmission

Each protocol must be resubmitted in full every three years. Resubmissions are intended to replace all previous submissions of a given protocol, as well as any amendments to the protocol. The resubmission should incorporate all of the approved amendments and any additional proposed changes. The resubmission must be complete enough to stand on its own without reference to the previously approved protocol. Existing protocols that are not approved through the triennial resubmission process on or before their anniversary date will be expired. **Once expired, the research must cease. Any animals remaining in The University of Southern Mississippi facilities must be transferred to another active protocol or will revert to the facility manager's care, who will make a recommendation to the IACUC on disposition of the animals. If appropriate, animals may be put up for adoption, released to the wild, or donated to a local zoo**.

VII. Process for Investigation

A. Process for Investigating Harm and/or Possible Non-Compliance

The IACUC has the responsibility of overseeing the protection of animals used in research. The IACUC exercises this responsibility by investigating complaints of harm due to a research process or Principal Investigators (or co-investigators) not following their approved research protocols. Principal Investigators are also required to promptly report to the IACUC any harm experienced by animals. Initial reports of harm or possible non-compliance should be brought to the attention of the IACUC Chair or any IACUC member. The Chair, in consultation with any other IACUC members as might be required, conducts the initial investigation. The purpose of the initial investigation is to, as quickly as possible, determine two points. First, does the assertion of harm or non-compliance have any merit (is it worth further investigation)? Second, are animals at risk if the research study is allowed to continue? To answer these questions the Chair may: interview the Principal Investigator and coinvestigators and others; examine research records requested from the investigators; and may personally inspect research facilities and equipment. This initial investigation should take place as quickly as possible, typically within a few days of receiving the initial information. If no harm or possible non-compliance is uncovered no further action is necessary. The IACUC will, however, temporarily suspend the animal use if this initial investigation uncovers evidence of harm

or non-compliance. Should this occur, the IACUC Chair will notify, verbally and in writing, the Principal Investigator, their department Chair or unit supervisor, and the Institutional Official that the research has been temporarily suspended.

Suspension of research activities, during which no research involving animals may be conducted, may be required by the IACUC. Although rare, a suspension is sometimes necessary to temporarily withdraw the IACUC's approval for a particular research protocol when evidence exists that harm has occurred to an animal being used in a research activity. The full IACUC, at a convened meeting, may suspend the IACUC's approval for a protocol if it is believed that harm has occurred and/or is likely to occur (or re-occur) if the research is allowed to continue. A suspension automatically begins an investigation of the circumstances resulting in the suspension. Such an investigation will comply with IACUC and university procedures for investigating research misconduct. Within two weeks of a suspension the IACUC will meet to consider the circumstances of the suspension and the resulting investigation to determine if the suspension should be lifted or the IACUC's approval terminated.

Complaints of harm or possible non-compliance that the Chair has found to have merit, regardless of whether a research protocol has been temporarily suspended, will be brought by the Chair to a special meeting of the IACUC within two weeks of the Chair's determination. At this meeting the IACUC will be presented with whatever facts have been collected thus far. The Principal Investigator, co-investigators, and any others with relevant information will be invited to present information to the committee. The IACUC will then decide if further investigation is needed or if sufficient information is available to determine whether harm or non-compliance has occurred. The IACUC will also decide if the research protocol should be continued as originally approved, reinstated (if temporarily suspended), suspended pending a further investigation by the IACUC or revisions by Principal Investigator, or terminated (the IACUC withdraws approval for the study).

Non-Compliance occurs when a Principal Investigator, or other researchers under the direction of the Principal Investigator either: (a) engages in research activities other than those approved in the original (or modified) research protocol; (b) continues to engage in approved research protocol activities beyond the time period specified in the approval period, or; (c) engages in any research activities involving animals without a research protocol previously approved by the IACUC. Investigation of non-compliance will follow IACUC and university procedures for investigating research misconduct. All instances of non-compliance will be reported by the IACUC to the designated university official for IACUC oversight. Some instances might require reporting to other local, state, or federal departments or agencies.

B. Reporting Concerns About Animal Care and Use

The system of regulatory oversight and compliance is founded upon trust between the regulatory agencies, the Institutional Official, the IACUC, the Sponsored Programs Administration, and the PI and his/her research team. The IACUC relies on each member of the community to act responsibly and correctly. The entire community bears a responsibility to uphold the ethical and regulatory requirements associated with animal

use. In this regard, it is critically important that the institution and its community demonstrate the ability to police itself. Consistent with its commitment to humane animal care and use, the University encourages anyone who perceives a problem with the way in which animals are housed, handled, or used in research or teaching to report their concerns. This includes the use of animals in ways that differ from the approved protocol. Such matters may be discussed with the individual's supervisor, the consulting veterinarian of the facility, the animal facilities manager, the IACUC Chair, the IACUC members, department chairs, or the Institutional Official. Information on contacting these individuals is available in the USM telephone book. Reports may be made anonymously. The IACUC will investigate complaints and take appropriate actions as necessary to alleviate the problem. Animal-related emergencies should be reported immediately to the animal facilities manager or the veterinarian.

VIII. IACUC Member Training

All members of the IACUC receive training upon joining the committee. They are expected to attend a training session offered by the IACUC Chair or an IACUC member designated by the Chair. In addition, new members are expected to familiarize themselves with the regulations, with IACUC and Sponsored Programs Administration policies and procedures, and by completing other training sessions as appropriate. In addition, IACUC members receive training in specific areas of animal care and use through the monthly IACUC meetings and through discussions of policy, procedure or scientific issues. All members are encouraged to attend IACUC training workshops sponsored by Scientists Center for Animal Welfare.

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